AMENDED IN SENATE JUNE 23, 2005

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 18, 2005

AMENDED IN ASSEMBLY APRIL 7, 2005

AMENDED IN ASSEMBLY FEBRUARY 11, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 71

Introduced by Assembly Members Chan and Frommer (Coauthors: Assembly Members Bass, Cohn, Evans, Gordon, Koretz, and Pavley)

January 3, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 71, as amended, Chan. Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would establish the Office of California Drug Safety Watch within the department and would require the office, among other duties, to establish a central repository of information about the safety and effectiveness of prescription drugs ~~frequently advertised on television,~~ *that belong to classes of drugs for which there have been*

recently published reports of safety concerns, that have been frequently advertised directly to consumers, and for which there are recently published systematically reviewed evidence-based research that includes research on side effects and safety issues. The bill would require the office to disseminate information to health care professionals and consumers through an Internet Web site~~,~~ *and* to request assistance from the University of California and California State University~~, and to rely on systematically reviewed evidence-based research~~.

This bill would require the department to impose a fee on any manufacturer of drugs sold in the state, in an amount based on the drug manufacturer's market share of the total amount of drugs sold in the state.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Since 1997, when the United States Food and Drug Administration (FDA) allowed drug manufacturers to advertise directly to consumers, the amount spent on advertising has risen dramatically.

(b) According to the United States General Accounting Office (GAO) report, the pharmaceutical industry spent $2.7 billion in 2001 on direct-to-consumer advertising. A December 6, 2004, New York Times report states that such spending has reached $3.8 billion.

(c) According to the same GAO report, while overall spending on drug promotion was less than spending on research and development ($19.1 billion versus $30.3 billion), spending on direct-to-consumer advertising is increasing at a faster rate than overall drug promotion spending or spending on research and development. Between 1997 and 2001, the increase in direct-to-consumer advertising was 145 percent compared to a 59 percent increase for research and development.

(d) Although the FDA is responsible for postmarket surveillance of prescription drugs, numerous concerns have been raised about the adequacy of these efforts.

(e) An unpublished internal FDA study from 2002 revealed that 18 percent of FDA scientists reported being pressured to approve a new drug "despite reservations about the safety, efficacy or quality of the drug."

(f) A 1999 FDA survey and a Kaiser Family Foundation survey both found that more than 50 million people respond to drug advertisements by asking their doctor whether the advertised medications might work for them. At the same time, both surveys showed that almost 60 percent of consumers found the side-effect warnings in these advertisements to be inadequate.

(g) Pressure to get new drugs to market, combined with the vast amount of drug marketing undertaken by manufacturers, make it difficult to address a threat once it is identified. Recent studies linking the use of popular, widely promoted prescription drugs to serious public health concerns point to the need for greater oversight to protect the public.

(h) Drugs that are frequently advertised to consumers present special safety concerns because direct-to-consumer advertising is likely to minimize potential side effects and safety concerns and because advertised drugs are likely to be highly utilized by Californians.

~~(h)~~

(i) Californians do not have a reliable central repository of information about prescription drug safety and effectiveness.

~~(i)~~

(j) California physicians and other prescribers could benefit from a reliable central repository of information about prescription drug safety and effectiveness.

~~(j)~~

(k) Various nationally respected sources of clinical information are available as sources for a central respository of information about prescription drug safety and effectiveness.

~~(k)~~

(l) Safer and more effective prescription drugs within a class may also be among the less expensive prescription drugs within that class, meaning that a reliable central repository of information about prescription drug safety and effectiveness would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Office of California Drug Safety Watch

111657. (a) There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall do all of the following, to provide Californians with information on the safety and effectiveness of prescription drugs:

(1) Establish a central repository of information about the safety and effectiveness of prescription drugs that are ~~frequently advertised on television.~~ *selected pursuant to subdivision (b). The repository shall not include information about any therapeutic class of drugs that is used primarily to treat mental illness.*

(2) Disseminate information to California health care professionals and consumers through an Internet Web site that shall include links to other relevant Web-based information that has been professionally reviewed and approved. *The Internet Web site shall include the following statement: "Many factors enter into selecting the proper drug for individual patients. Before changing any medication, a patient shall consult with his or her treating physician or other prescriber."*

(3) Ensure that the dissemination of information is done in a culturally competent manner and addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available. *When there is no evidence supporting the differential impact of medication among various demographic groups, it shall be noted on the Internet Web site.*

~~(4) In selecting therapeutic classes of drugs about which to develop information, the office shall choose the four most frequently advertised classes of drugs for which there is recently published systemically reviewed evidence-based research.~~

~~(5) Request appropriate units of the University of California and the California State University to provide assistance.~~

~~(6) Rely on systematically reviewed evidence-based research.~~

~~(b) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.~~

(b) In selecting therapeutic drugs about which to develop information, the office shall only include classes of drugs that have all of the following characteristics:

(1) Classes of drugs for which there have been recently published reports of safety concerns.

(2) Classes of drugs that have been frequently advertised directly to consumers.

(3) Classes of drugs for which there are recently published systemically reviewed evidence-based research that includes research on side effects and safety issues.

(c) The office shall request the appropriate units of the University of California and the California State University to provide assistance in implementing this article.

(d) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.

(e) The office shall rely on systemically reviewed evidence-based research.

(f) The process that the office uses to identify relevant research and standards of clinical evidence shall be transparent and publicly available.

111657.1. For purposes of this article, the following terms have the following meanings:

~~(a) "Evidence-based research" means prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups.~~

(a) "Evidence-based research" means research that is based on clinical evidence, including therapeutic outcomes, and that uses a hierarchy of evidence to evaluate the reliability of the research. In well-conducted research, the hierarchy of evidence, from highest to lowest, is the system review of randomized clinical trials, individual randomized clinical trials, controlled trials, cohort studies, and case control studies.

(b) "Systematically reviewed" means review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to estimate the comparative effectiveness and safety of health care treatments. A systematic approach to reviewing the evidence

increases the reliability of the results, and the transparency of the procedures.

~~(c) "Most frequently advertised classes of drugs" means the therapeutic classes of drugs most frequently advertised on television for the six-month period prior to the date the office begins compiling the drug safety and effectiveness information required by this article. Frequently advertised classes of drugs shall not include any therapeutic class that is used primarily to treat mental illness.~~

111657.2. (a) There is hereby imposed, pursuant to this section, a fee on manufacturers of drugs sold in the state.

(b) (1) The specific fee to be assessed on a drug manufacturer shall be established by the State Department of Health Services, to the maximum extent practicable, on the basis of a drug manufacturer's market share of the total amount of drugs sold in the state.

(2) A fee shall not be assessed on a drug manufacturer that can demonstrate, as determined by the State Department of Health Services, that it does not manufacture drugs that have the characteristics described in subdivision (b) of Section 111657.

(c) The fee shall be assessed and collected annually by the State Board of Equalization in accordance with Part 22 (commencing with Section 43001) of Division 2 of the Revenue and Taxation Code. The fees collected shall be deposited in the Drug Safety Watch Fund, which is hereby established in the State Treasury. Moneys in the fund shall be expended, upon appropriation by the Legislature, for the purposes of this article, including the costs of the State Board of Equalization for collection and administration of fees. All interest earned on the moneys that have been deposited into the Drug Safety Watch Fund shall be retained in the fund.

(d) The fees collected pursuant to this section and the earnings therefrom shall be used solely for the purposes of implementing this article. The department shall not collect fees pursuant to this section in excess of the amount reasonably anticipated by the department to fully implement this article. The department shall not spend more than it collects from the fees, and the earnings thereon, in implementing this article.

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